Docket No.: NY-MSI 203-US

RECEIVED
CENTRAL FAX CENTER

AMENDMENTS TO THE CLAIMS

OCT 0 2 2008

1. (Currently amended)   A program storage comprising computer-executable instructions for method of continuously analyzing trial data of an ongoing clinical trial, the method comprising the steps of said computer-executable instructions being for:

accessing a trial database comprising trial data of subjects in an ongoing blinded clinical trial comprising a multi-arm study;

accessing a blinding database comprising subject identifiers and associated study group identifiers, wherein a subject's study group being identifiable by a study group identifier;

generating a grouped database from the trial database and the blinding database for statistical analysis, the grouped database grouping the trial data of the subjects based on their study group;

performing a statistical analysis on the accessed trial database without suspending the ongoing blinded clinical trial;

determining whether the result of the statistical analysis exceeds a predetermined threshold value; and

if it is determined that the result of the statistical analysis does not exceed the predetermined threshold value, then repeating the steps of said computer-executable instructions for accessing a trial database, performing and determining while the blinded clinical trial is ongoing.

2. (Currently amended)   The program storage of method according to claim 1, prior to the step of performing a statistical analysis, further comprising the steps of computer-executable instructions for:

reading a user defined criteria that defines the level of cleanliness of the trial data for statistical analysis; and

2

55280556.1

PAGE 6/29 * RCVD AT 10/2/2008 2:51:08 PM [Eastern Daylight Time] * SVR:USPTO-EFXRF-6/32 * DNIS:2738300 * CSID:2123183400 * DURATION (mm-ss):07-32

retrieving only those trial data that meet the user defined criteria from the trial database.

3.   (Currently amended)   The program storage of ~~method according to~~ claim 1, further comprising ~~the step of~~ computer-executable instruction for waiting for a predetermined time period prior to the repeating said computer-executable instruction for accessing a trial database, performing and determining while the blinded clinical trial is ongoing ~~step~~ if it is determined that the result of the statistical analysis does not exceed the predetermined threshold value.

4.   (Canceled)

5.   (Currently amended)   The program storage of ~~method according to~~ claim 1, further comprising ~~the step of~~ computer-executable instruction for storing the grouped database in a memory device that is inaccessible by any user.

6.   (Currently amended)   The program storage of ~~method according to~~ claim 1, wherein ~~the step of~~ said computer-executable instruction for performing a statistical analysis ~~is executed~~ without locking the trial database.

7.   (Currently amended)   The program storage of ~~method according to~~ claim 1, further comprising ~~the steps of~~ computer-executable instructions for:
        reading a predefined criteria that defines the level of cleanliness of trial data required for analysis; and
        retrieving only those trial data that meet the predefined criteria from the trial database.

8.   (Currently amended)   The program storage of ~~method according to~~ claim 7, further comprising ~~the step of~~ computer-executable instruction for storing the grouped database in a memory device that is inaccessible by any user to preserve the blindness of the ongoing blinded clinical trial.

3

9.   (Currently amended)   The program storage of ~~method according to~~ claim 1, further comprising ~~the step of~~ computer-executable instruction for alerting a user if it is determined that the result of the statistical analysis exceeds the predetermined threshold value.

10.   (Currently amended)   The program storage of ~~method according to~~ claim 9, wherein the predetermined threshold value includes a predetermined statistical significance value.

11.   (Currently amended)   The program storage of ~~method according to~~ claim 10, wherein ~~the step of~~ said computer-executable instruction for performing a statistical analysis comprises ~~the steps of~~ computer-executable instructions for:

retrieving a user defined statistical model; and

running the retrieved user defined statistical model on the trial database.

12.   (Currently amended)   A program storage comprising computer-executable instructions for ~~method of~~ continuously analyzing trial data of an ongoing blinded clinical trial, ~~the method comprising the steps of~~ said computer-executable instructions being for:

accessing a trial database comprising blinded trial data of subjects in an ongoing blinded clinical trial comprising a multi-arm study;

accessing a blinding database containing subject identifiers and associated study group identifiers, each study group identifier identifying to which study group an associated subject belongs;

producing a grouped database from the trial database and the blinding database, the grouped database grouping the trial data according to the study group;

performing a statistical analysis on the produced grouped database without suspending the ongoing blinded clinical trial;

4

55280556.1

PAGE 8/29 * RCVD AT 10/2/2008 2:51:08 PM [Eastern Daylight Time] * SVR:USPTO-EFXRF-6/32 * DNIS:2738300 * CSID:2123183400 * DURATION (mm-ss):07-32

determining whether the result of the statistical analysis exceeds a predetermined threshold value; and

if it is determined that the result of the statistical analysis does not exceed the predetermined threshold value, then repeating said computer-executable instructions for the above steps of: accessing a trial database, producing a grouped database, performing a statistical analysis, and determining while the blinded clinical trial is ongoing.

13. (Currently amended)   The program storage of method according to claim 12, prior to the step of performing a statistical analysis, further comprising the steps of computer-executable instructions for:

reading a user defined criteria that defines the level of cleanliness of trial data for statistical analysis; and

retrieving only those trial data that meet the user defined criteria from the trial database for statistical analysis.

14. (Currently amended)   The program storage of method according to claim 12, further comprising the step of computer-executable instruction for storing the produced grouped database in a memory device that is inaccessible by any user.

15. (Currently amended)   The program storage of method according to claim 12, wherein the step of said computer-executable instruction for performing a statistical analysis is executed without locking the trial database.

16. (Currently amended)   The program storage of method according to claim 12, further comprising the step of computer-executable instruction for alerting a user if it is determined that the result of the statistical analysis exceeds the predetermined threshold value.

5

17.   (Currently amended)   The ~~program storage of~~ method ~~according to~~ claim 16, wherein the predetermined threshold value includes a predetermined statistical significance value.

18.   (Currently amended)   A system for continuously analyzing an ongoing clinical trial comprising:

a storage device operable to store a trial database comprising trial data of subjects in an ongoing blinded clinical trial comprising a multi-arm study;

a processor coupled to the storage device; and

an analysis program executable by the processor and operable to:

access the ~~trail~~ trial database to retrieve the trial data;

access a blinding database comprising subject identifiers and associated study group identifiers, wherein a subject's study group being identifiable by a study group identifier;

generate a grouped database from the trial database and the blinding database for statistical analysis, the grouped database grouping the trial data of the subjects based on their study group;

perform a statistical analysis on the trial database without suspending the ongoing blinded clinical trial;

determine whether the output result of the statistical analysis exceeds a predetermined threshold value; and

repeat the statistical analysis while the blinded clinical trial is ongoing if it is determined that the result of the statistical analysis does not exceed the predetermined threshold value.

19.   (Original)   The system according to claim 18, wherein the analysis program is further operable to:

read a user defined criteria that defines the level of cleanliness of trial data for statistical analysis; and

6

retrieve only those trial data that meet the user defined criteria from the trial database.

20.   (Original)   The system according to claim 18, wherein if the analysis program determines that the result of the statistical analysis does not exceed the predetermined threshold value, then the analysis program waits for a predetermined time period prior to repeating the statistical analysis.

21.   (Canceled)

22.   (Previously presented)   The system according to claim 18, further comprising a memory device coupled to the processor and being inaccessible to any user, wherein the grouped database is stored only in the memory device.

23.   (Original) The system according to claim 18, wherein the analysis program performs the statistical analysis without locking the trial database.

24.   (Original)   The system according to claim 18, wherein the analysis program is further operable to alert a user if it determines that the result of the statistical analysis exceeds the predetermined threshold value.